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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,278	10/10/2001	Carrie L. Fischer	PZ010P2	5790
22195	7590	01/22/2004		
HUMAN GENOME SCIENCES INC 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850				
			EXAMINER SIEGLER, ALEXANDER H	
			ART UNIT 1637	PAPER NUMBER

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/973,278

Applicant(s)

FISCHER ET AL.

Examiner

Alexander H. Spiegler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-50 is/are allowed.
- 6) ☒ Claim(s) 51-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

## **DETAILED ACTION**

### ***Status of the Application***

1. This action is in response to Applicants' response, filed on October 29, 2003. Currently, claims 25-70 are pending. This action is made FINAL. Any objections and rejections not reiterated below are hereby withdrawn. Specifically, the 101 rejection has been withdrawn, in view of Applicants' arguments and the teaching in the specification (page 457) that the claimed protein functions solely in the production of IL-10. The 112, 1<sup>st</sup> paragraph written description rejection, with respect to Claims 37-50, has been withdrawn in view of Applicants' amendment to the claims, providing the functional recitation of "wherein said protein can induce the production of IL-10".

### **THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS**

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 51-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51-70 are indefinite because it is not clear as to whether the claim language is intended to be "open" (i.e., consisting of) or "closed" (i.e., comprising) claim language. Claims 51-70 recite, "an isolated protein *consisting of* a fragment of...SEQ ID NO: 164, wherein said fragment is *at least* 30 contiguous amino acids residues in length". Therefore, the claim recites,

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“closed,” claim language (i.e., consisting of), followed by “open” claim language (i.e., at least, which is equivalent to “comprising”). That is, the recitation of “at least” could comprise a fragment of SEQ ID NO: 164 and a plurality of possible contiguous amino acid residues flanking said fragment of SEQ ID NO: 164. Accordingly, it is not clear as to whether the claim intends to limit the claims to only fragments of SEQ ID NO: 164 (with no flanking sequences), or fragments of SEQ ID NO: 164 (including flanking sequences).

#### MAINTAINED REJECTION

#### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 51-70 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 51-70 are directed to isolated proteins comprising contiguous amino acid residues of SEQ ID NO: 164. Claims drawn to proteins “consisting of...a fragment...at least” (i.e., comprising) 30 or 50 contiguous amino acid residues of SEQ ID NO: 164, includes a large genus of proteins, having unique functional activities, whereas applicants only disclose one member of the genus (i.e., SEQ ID NO: 164) and haven’t disclosed any other proteins having portions of SEQ ID NO: 164. In addition, proteins having any 30 or 50 residues of SEQ ID NO: 164 would

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be expected to have unique functional activities, wherein the specification has not disclosed any proteins having functional activities different from those of SEQ ID NO: 164. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claims.

*Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the invention. The invention is, for purposes of the written description inquiry, *whatever is now claimed* (See page 1117)." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed (See Vas-Cath at page 1116)."

The skilled artisan cannot envision the detailed chemical structure of the encompassed proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly

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allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

### **Applicants Arguments**

Applicants argue the amended claims fully meet the written description requirement, since one of ordinary skill in the art can readily envision all species encompassed by the claims, and that Applicants had possession of the polypeptides encompassed by the rejected claims. (See Applicants remarks on page 8) Applicants also argue that given the amendment to the claims reciting polypeptides 90% or 95% identical to SEQ ID NO: 164, which adds functional language of inducing IL-10 activity, the skilled artisan would be able to identify "every single one" of the claimed polypeptides. (See Applicants remarks on page 8)

### **Response to Applicants Arguments**

Applicants' arguments have been considered, but are not persuasive for the following reasons. First, Applicants have amended the claims to recite, "an isolated protein consisting of a fragment of ...SEQ ID NO: 164, wherein said fragment is at least 30 contiguous amino acids residues in length". Therefore, the claim recites, "closed," claim language (i.e., consisting of), followed by "open" claim language (i.e., at least, which is equivalent to comprising). Thus, the claims could be interpreted as essentially reading on the "open" claim language, which includes a large genus of proteins, having unique functional activities, whereas applicants only disclose

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one member of the genus (i.e., SEQ ID NO: 164). Additionally, Applicants' arguments are not persuasive, since Applicants have not included functional language for the fragments of SEQ ID NO: 164. As Applicants' point out, the skilled artisan would be able to identify those sequences that are 90% or 95% identical to SEQ ID NO: 164 and have the function of inducing the production IL-10. However, absent any functional language, the skilled artisan would not be able to identify those sequences consisting of a fragment of at least 30 or 50 contiguous amino acids of SEQ ID NO: 164. Accordingly, Applicants can overcome this rejection by adding functional language to the claims.

For these reasons and those of record, the rejection is maintained.

### *Conclusion*

6. Claims 25-50 are allowable.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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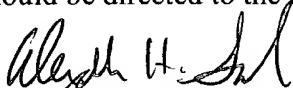
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

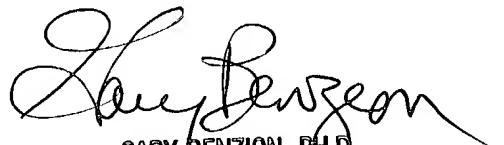
*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (571) 272-0788. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (571) 272-0747. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Alexander H. Spiegler  
January 20, 2004

  
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